

REMARKS

This Amendment responds to the final office action mailed February 27, 2007 (the Office Action). The Office Action was carefully reviewed and the following remarks are intended to fully address the concerns raised therein.

Receipt of the Advisory Action dated May 11, 2007 is acknowledged. Entry of the Amendment of April 25, 2007 is NOT requested; instead, the present Preliminary Amendment is submitted for entry as per the attached Request for Continued Examination.

The Examiner is thanked for the courtesy of an interview conducted June 24, 2007. Figures in the case were reviewed, along with the attached Figures A, B, and C. Figure A is a cross-section through a human showing the prostate and the rectum, which are labeled P and R, respectively. The same image is shown in Figure B, with the line D indicating the zone where about 80% of the radiation is received. Figure C shows another cross-section of a human patient with a filler, labeled "Agent", has been placed between a prostate gland P and a rectum R.

The prior art in the case was discussed, with the undersigned representing that the arguments of record were effective to overcome the prior art. The claims language "treating the second tissue location with the therapeutic a dose of radiation" was offered by the undersigned to address the Examiner's concerns as expressed in the Office Action. The undersigned understands that the parties agreed that the concerns about "relative terminology" in the claims are now moot.

Status of Claims

Claims 1-10 and 13-25, 27, and 29-62 are pending. Claims 17-25, 27, and 29-38 and 62 are under examination. Claims 42 and 58 are cancelled without prejudice for future prosecution.

Withdrawn claims 1, 39, 40, and 44 are amended for consistency with the claims under active prosecution. Withdrawn claim 41 is amended for a typographic error and clarity.

Withdrawn claim 56-57 were amended for antecedent basis. Claim 17 was amended as described above, and further amended to clarify that it is the device that degrades, e.g., as at Example 2 of the specification.

New claim 63 was added, with support in the specification at, e.g., page 5, line 17. New claim 64 is provided to specify a radiation dose of at least 70 Gy as per the specification at, e.g., page 20, line 8.

Status of Withdrawn Claims

Claims 1-10, 13-16, and 39-61 have been withdrawn by the Examiner. Claims 33 and 35 are linking claims that link the inventions of Groups I, III, and IV. Applicant has elected Group IV having claims 17-38, and made a species election of item (h) polyethylene glycol.

Withdrawn claims are not cancelled herein

The Office Action states that the nonelected claims must be cancelled (page 8 of the Office Action) as per 37 C.F.R. §1.144 and MPEP §821.01. The withdrawn claims do not require cancellation, however, because they are linked by generic claims 33 and 35. The status of these claims as generic was established by the Patent Office and is of record in the restriction requirement dated June 23, 2006.

MPEP §821 explains that §§821.01 - 821.04 control claims held to be drawn to nonelected inventions, including claims drawn to nonelected species or inventions that may be eligible for rejoinder. MPEP §821.04 explains that “when all the claims directed to the elected invention are in condition for allowance, and the nonelected invention(s) should be considered for rejoinder.” It is only when the withdrawn claims are ineligible for rejoinder that their cancellation is required. Rejoinder of the withdrawn claims is requested upon allowance of the generic claims.

Rejection of claims

Claims 17-25, 27, 29-38 and 62 were rejected under 35 U.S.C. §103(a) as being unpatentable over Tihon et al. (U.S. Pat. No. 5,499,994) and Gokcen (U.S. Pat. No. 6,913,744). This rejection represents a renewal of a previous rejection in spite of Applicant's previous amendments of record.

The Office Action's basis for the rejections

The Office Action sets forth its rejection of the claims by first explaining its reasoning (pages 3-5) and then addressing the Applicant's previous arguments (pages 6-7). Each of its points are taken in the order presented in the Office Action.

(1) The cited art teaches the opposite of the claimed tissue displacement

The Office Action characterizes Tihon et al. as teaching treatment of hypertrophy of the prostate gland and dilation devices or swellable materials for the urethra (Office Action page 3) and describes the swellable aspect at pages 3-4 of the Office Action. The Office Action characterizes Gokcen as teaching a method and composition for treating prostate cancer whereby suitable methods of treatment disclosed include administering radiation (Office Action page 4) and active agents such as antibiotics (Office Action page 4-5).

A prima facie case of rejection must supply every claimed element. The Office Action's rejection necessarily requires that the urethra and the prostate are supplying the claimed first tissue and second tissue. The Office Action does not explain, however, how this could possibly provide the claimed (claim 17) aspect of introducing a biocompatible, biodegradable filler to between a first tissue location (prostate) and a second tissue location (urethra) to increase a distance between the first tissue location (prostate) and the second tissue location (urethra). In

fact, Tihon et al. teaches a device that is placed inside a urethra that does not increase a distance between any one tissue and any another tissue, and certainly not a distance between a urethra and a prostate gland. Specifically, Tihon et al. teaches a device 22, see Figures 2 and 3, that is placed inside urethra 12 that expands in response to swelling of hydrophilic means 32. The device is inside the urethra and therefore forces the urethra against the surrounding tissue. The device thus apparently does not increase a distance between a first and a second tissue. In fact, it apparently presses the urethra against the prostate and decreases the distance between these two tissues and does the *exact opposite* of what is claimed.

For these reasons, it is respectfully submitted that no prima facie case of obviousness has been made and withdrawal of the obviousness rejection is requested.

(2) The cited art teaches the opposite of the claimed biodegradable filler

Amended claim 17 states that a biocompatible, biodegradable filler device is removed by biodegradation of the filler device in the patient. Tihon et al. and Gokcen do not teach or suggest this feature in combination with the other claimed features.

Tihon et al. describes only devices that are not degradable and are not removed by biodegradation, regardless of whether or not the devices have degradable materials captured therein. For instance, Tihon et al. explains that a hollow member 24 and a covering 33 (see Tihon et al. Figure 3) are part of the device; these elements are not degradable. Tihon et al. explains that the device must be removed, e.g., at column 9 lines 61-67, something that must be done regardless of the use of other materials interior to the device.

For these reasons, withdrawal of the obviousness rejection is requested.

(3) There is no motivation to combine the cited art

It is agreed that Tihon et al. do not teach administering radioactivity or applying an antibiotic to a tissue (Office Action page 4).

The Office Action provided the following explanation for combining the references:

“It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the radiation methods and active agents, such as antibiotics, as taught by Gokcen within the treatment methods of Tihon et al. One of ordinary skill in that art would be motivated to do so with a reasonable expectation of success because Gokcen teaches that suitable and effective methods for treatment of prostate cancer include [sic] administering radiation, dependent on factors such as age of patient and severity of condition and also teach that active agents, such as antibiotics are added to the composition to promptly relieve symptoms of acute prostatic infections. The expected result would be an improved, safe and effective method for treating prostatic conditions in a patient.”

The Office Action states that it would have been obvious to combine the references “because Gokcen teaches that suitable and effective methods for treatment of prostate cancer include [sic] administering radiation, dependent on factors such as age of patient and severity of condition and also teach that active agents, such as antibiotics are added to the composition to promptly relieve symptoms of acute prostatic infections.” But it is not enough to describe what Gokcen teaches. There must be a reason to combine Gokcen with Tihon et al. It is a well-settled principle that just because references can be combined or modified does not render the

resultant combination obvious unless the prior art also suggests the desirability of the combination. See MPEP 2143.01. Withdrawal of this rejection is requested.

(4) The claims are not diminished by relative terminology

The Office Action indicated that the claim language “administering a dose of radioactivity to the second tissue location so that the presence of the filler causes the first tissue location to receive less of the dose of radioactivity compared to the amount of the dose of radioactivity the first tissue location would receive in the absence of the filler” is relative in nature and thus lacks patentable weight. This language, however, is plainly clear and definite, and thus has patentable weight. There is no legal basis for not giving patentable weight to a clear and definite limitation in a method claim.

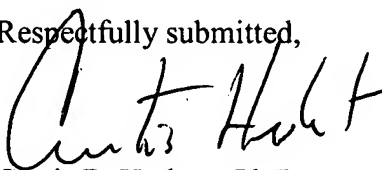
(5) Claimed comparison of radioactivity dose

As previously argued, Tihon et al. and Gokcen do not teach or suggest, among other things, the limitation of claim 17 directed to using the filler to increase a distance between the first tissue location and the second tissue location so that the presence of the filler causes the first tissue location to thereby receive less of a dose of radiation that is applied. Therefore there is no prima facie case of obviousness since each and every claimed limitation is not present in the prior art. The Office Action addresses this argument by arguing that this limitation has no patentable weight. As explained, however, this limitation should be given patentable weight such that the claims should be allowed.

Request for allowance

Multiple reasons that are solely dispositive for allowance of the claims are presented. Accordingly, allowance of the claims is requested. The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Curtis Herbert", written over the typed name.

Curtis B. Herbert, Ph.D.

Registration No. 45,443

Customer No. 62274
Dardi & Associates, PLLC
US Bank Plaza, Suite 2000
220 South 6th Street
Minneapolis, Minnesota 55402
Telephone: (612) 605-1038